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**Response to Final Office Action dated October 6, 2006****Overview**

5 Applicant amended independent claims 1, 10, 17, and 20.  
Applicant cancelled dependent claims 7 and 15. Applicant  
cancelled claims 21-25. The present invention is US 2005 0187500  
A1 and referenced by paragraph number. Applicant submitted a  
new affidavit. This response will address the Office Action's  
10 position at page 3, line 8 through page 4.

**Response to the 103 Rejection**

15 The Office Action rejected claims 1-31 under 35 U.S.C.  
section 103 as being unpatentable over Cone '200 in view of  
Ladd, along with Barak '081.

20 Applicant respectfully states amended independent claims  
are patentably distinct over the combination of cited  
references.

25 There is not teaching, motivation or suggestion to modify  
any of the prior art references to combine a check valve in with  
a pressure sensor, at the physical location in the pneumatic  
circuit as claimed, and a pneumatic circuit to calculate venous  
refill time. See Ex parte Re Qua, 56 USPQA 279 (C.C.P.A. 1942)  
("[t]here is no suggestion in either [prior art] patent as to  
how the features of the two devices could be combined so as to  
meet the structure claimed.") Furthermore, the Examiner has not  
30 explained why the combination of references is proper. See Ex  
parte Skinner, 2 USPQ2d 1788, 1790 ("When the incentive to  
combine the teachings is not readily apparent, it is the duty of

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the examiner to explain why combination of the reference teachings is proper. . . .Absent such reasons or incentives, the teachings of the references are not combinable."). More importantly, the Examiner cannot use the Applicant's invention as a "template" to reconstruct the claimed invention. See *In re Fritch*, 972 F.2d 1260 (Fed.Cir.1992) (quoting *In re Fine*, 837 F.2d 1071, 1075) ("It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that "[o]ne cannot use hindsight construction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.").

The Office Action states, "However, Cone doesn't disclose a check valve." Referring to the Applicant's previous affidavit, a check valve is not a solenoid valve. "A solenoid valve requires electricity and a control signal from electronics to operate". See Wudyka June 2006 Affidavit at paragraph 3.

The Office Action states, "Ladd teaches in figures 1-3 a medical irrigation pump and system comprising a first bladder 17a, a second bladder 17b, a pressure sensor means 46, a check valve 62, operably connected to a fluid source 61, for preventing fluid leakage back through a pump 14, for monitor bladder pressure during inflation." Applicant respectfully disagrees Ladd provides any information that would motivate one to use the check valve as claimed. See *Ex parte Re Qua*. Also, see Inventor Affidavit (Dec 2006).

Ladd does not disclose anything about the use of its check valve 62, at col. 4, line 12 or at Figure 2B. Ladd does not

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5 teach or suggest the single check valve and single pressure  
sensor, as claimed in the present invention. Furthermore, Ladd  
is not a relevant reference because Ladd is directed to  
maintaining fluid flow when changing emptied fluid reservoirs as  
10 part of a multiple reservoir system for irrigation. See Ladd  
Abstract, Summary and Inventor Affidavit (Dec2006). By contrast  
the present invention provides sequential gradient compression  
for preventing the pooling of blood in a patients extremity. See  
Applicant's Invention at Table 1. Blood pooling can lead to a  
15 blood clot, which can be fatal. Providing a reliable estimate  
of a person's blood refill time helps to prevent pooling, as the  
compression cycle is better suited to that person's individual  
physiological characteristics. The device as claimed provides a  
reliable, low cost and straightforward solution to a potentially  
20 serious consequence. See McGinley v. Franklin Sports Inc., 262  
F.3d 1339 (Fed.Cir. 2001) (The genius of invention is often a  
combination of known elements which in hindsight seems  
preordained. To prevent hindsight invalidation of patent  
claims, the law requires some "teaching, suggestion or reason"  
25 to combine cited references. . . When the art in question is  
relatively simple, as is the case here, the opportunity to judge  
by hindsight is particularly tempting. Consequently, the tests  
of whether to combine references need to be applied  
rigorously.")

30 The combination of references still does not show that a  
check valve can substitute for the solenoid valve in Cone '200.  
The Office Action states, in part, "Barak teaches in figures 1-  
10 a compression treatment system comprising relief valves,  
solenoid valves and check valves (section 0063) and the relief  
valves can be substituted for the solenoid valve (section  
0059)." Barak teaches three replacement elements or components

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are needed to remove a solenoid valve from a pneumatic circuit. See Affidavit Dec 2006, Barak [0012], [0063]. Barak also teaches placing these replacement elements at the sleeve, nearer the inflatable bladders (92), not as part of the pneumatic circuit located at the portable control device (91). See id.

By contrast, the present invention claims its check valve [54] is located between the fluid source [50] and solenoid valves [58, 60], as part of the controller [14] which is located in a housing [12]. Barak's pneumatic circuit teaches away from the present invention when its circuit (94, 95, 96) is located at the sleeve (92), and furthermore as disclosed, Barak has two pressure sensors (PS1, PS2) as compared to the present invention that has a single pressure sensor [66] (as originally claimed). The above stated differences will require substantial reorganization of the Barak elements without any suggestion or motivation. See In re Fritch.

At Barak paragraphs [0012] and [0063], Barak clearly teaches and discloses three elements to replace a solenoid valve. Barak clearly states, "Solenoid valves are replaced, in this embodiment, by self-operated relief valves 95, ... Each relief valve (except the last one) is bypassed with a conduit section including a check valve 96 to allow deflating of the cell." See Barak [0063]. Nowhere in Barak, alone or in combination of figures and text, does Barak teach or disclose a check valve [96] substitutes for a solenoid valve. The check valve [96] is not the same as a solenoid valve. See Wudyka June 2006 Affidavit. Also, see Wudyka December 2006 Affidavit (discussing what Barak teaches in paragraphs [0059], [0063] and Figures 9 and 10).

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The Office Action, at page 3, states in part "It would have been obvious to one having ordinary skill in the art that the check valve as taught by Ladd could be substituted for the solenoid valve disclosed by Cone." This statement provides no evidence of teaching or disclosure in Ladd or Cone, as to the role or use of a check valve in cooperation with a single pressure transducer, as claimed, in calculating venous refill time. Ladd, Cone and Barak have no disclosure about venous refill time. Ladd, as stated above, has no disclosure whatsoever on the role or use of its check valve. There is no teaching, except in the present invention, that the check valve prevents fluid leakage from the bladder while the pressure sensor monitors bladder pressure to determine venous refill time. See Applicant at paragraphs [0052, 0080-0087].

Furthermore, Ladd uses its check valve for a different purpose. See Inventor Affidavit (Dec 2006). The inventor suggests the Ladd reference would not provide a productive result or solution, if followed. See *id.*, See U.S. v. Adams, 338 US 38 (1966).

There is no cited reference disclosing or teaching the single pressure sensor in combination with the check. Furthermore, Barak provides no motivation or teaching that the Ladd check valve can be substituted for Cone solenoid valve. The Office Action's prima facie case of obvious is unsupported. See *In re Qua*.

The Office Action describes a number of benefits when removing a solenoid valve from a pneumatic circuit. The Office Action states in part, "Substituting the check valve for the solenoid valve would provide miniaturization and mechanical simplification of the portable pressure system. Using a check

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valve versus a solenoid valve would make the system smaller, lighter and have longer independent operation." The Applicant acknowledges these benefits, but the Applicant's benefit from the check valve is that no control signal is needed to activate when calculating venous refill time. This reduces system complexity and cost, as stated in the Applicant's June 2006 Affidavit. See *Ex parte Franklin*, 41 USPQ 43 (Pat. Off. Bd. App. 1938) ("[I]f it were obvious to install applicant's device to increase ..., the device would have been used years ago"). Also, the Applicants affidavit supports evidence of secondary considerations. See *Cable Elec. Prods., v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881, 887 (Fed. Cir. 1985) ("[e]vidence of secondary considerations is always to be considered".)

The Patent Office is not allowed to use the Applicant's invention as a blueprint for combining references. See *In re Fritch*. The Office Action states, "Barak makes a comparison between the solenoid valve and the relief valve. However, one of ordinary skill in the art would recognize that if a solenoid valve is being used to block the flow of air, then it is interchangeable with a check valve. Clearly a check valve can operate without an electrical signal from a controller." Applicant agrees with the last sentence as supported in his June 2006 Wudyka Affidavit.

The Office Action states, in part, "Barak makes a comparison between the solenoid valve and the relief valve. However, one of ordinary skill in the art would recognize that if a solenoid valve is being used to block the flow of air, then it is interchangeable with a check valve. Clearly a check valve can operate without an electrical signal from a controller."

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5 The Office Action has not cited in the references where a solenoid valve is being used to block air alone or in combination with the single pressure transducer, as claimed in the present invention for measuring venous refill time. See In re Qua.

10 Applicant does not agree that one skilled in art would be motivated, using Barak for teachings and suggestions to substitute the check valve for a solenoid valve along with Ladd. There is no suggestion or teaching in Barak that check valve [96] is being used to block air flow. Barak teaches a check valve 96 is to deflate the cell at paragraph [0063]. Also, the check valve and pressure relief valve are combined to replace the solenoid valve, which teaches away from the present problem to be solved.

15 Emphasis, on block air flow, is added to point out, respectfully to the Examiner that the invention uses a check valve, passively operated and without electricity and a control signal, to prevent the leakage of air from the bladder during venous refill time measurement.

20 The Office Action has not shown in any cited reference, the use of the check valve as physically located in the Applicant's pneumatic circuit with a pressure sensor for measuring venous refill time, as claimed. Even if the Examiner disagrees, the Office Action has not shown the proper motivation in a combination of references, without the Applicant's invention as the blueprint to supply the missing information, the use of a single check valve and a single pressure sensor to determine venous refill time. Without more, the Applicant is entitled to his invention as the elements as claimed are not found in the

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prior art in a single reference or any combination of references with the proper motivation or teaching to combine. The Office Action is reading this result into Barak to substitute into Cone the Ladd check valve to practice the claimed invention. This hindsight is impermissible. See In re Fritch. Barak only teaches the check valve is to "allow deflating of the cell." See Barak at paragraph [0063].

The Applicant respectfully requests allowance of the amended independent claims and the dependent claims depending therefrom based on allowable independent claims.

Applicant respectfully requests an Examiner interview, if the above amendments do not place this application in a condition of allowance. Applicant authorizes the Commissioner of Patents to charge deposit account 190254 for any late fees or charges necessary to avoid abandonment. I can be reached direct at (508) 261-8476 or [Edward.jarmolowicz@tycohealthcare.com](mailto:Edward.jarmolowicz@tycohealthcare.com).

Respectfully yours,



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DEC 01 2006

December 2006

Commissioner for Patents  
Attention of Examiner Michael A. Brown  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313

Dear Examiner:

I am an inventor of U.S. Patent Application Serial No. 10/784,323.

The Barak Patent application, US-2006/0161081, discusses replacing a solenoid valve with a self operating pressure relief valve and check valve in section 0063. The relief /check valve combination acts pneumatically in a way that is not comparable to the check valve (54) in US 2005/0187500. The check valve in Perry is located, pneumatically, before the solenoid valves that control air flow to the bladders of the inflatable garment. The pressure relief valve and check valve combination mentioned in Barak is an alternate to using a solenoid valve. The pressure relief / check valve combination in Barak directly controls the inflation/deflation cycle of the bladders in the inflatable garment. The check valve in Perry is not integral to the pressurization of the bladders in the inflatable garment. Its purpose is to hold pressure during vascular refill detection. The pressure relief /check valve combination in Barak does not teach the use of a check valve in Perry. The functionality employed in these two cases is polar opposite.

The Ladd patent field of invention is medical irrigation, which is quite different from DVT prophylaxis. The check valve in the pneumatic circuit of the Ladd patent will stop air from passing back through the pump, under the state of inflation of the fluid bladder squeeze assemblies. This is a very different application of technology from Vascular Refill Detection technology. The Ladd invention generally inflates all of the assemblies to one pressure based on the manifolding of the pump output. When Vascular Refill Detection technology is employed in Perry et al, only one

bladder of the inflatable garment retains pressurized air, while any other bladder is allowed to fully depressurize. The check valve in Perry is used to hold only that small amount of pressure in one bladder at the time of the Vascular Refill measurement.

Avoidance of leakage during vascular refill detection is critical to a successful measurement. Holding a small pressure in way that minimizes all variation requires the check valve. Here the check valve is low cost, small, and requires no software control logic, which reduces complexity. A leakage in Ladd's medical irrigation system can be overcome by starting the pumping means. The Ladd invention does not have a critical need around leakage. Ladd has no leakage issue and I would not be inclined to use Ladd to resolve leakage issues faced in the present invention.

Additionally, the Perry invention performs bladder inflation in a sequential manner with a resulting pressure that is decreasing pressure gradient from the distal to proximal. The Ladd invention inflates simultaneously and does not employ sequential gradient pressures from bladder to bladder.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sincerely yours,

  
Scott Wudyka

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